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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/555,640	08/10/2000	QUANG TRI NGUYEN	045636-5033	1376

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EXAMINER

PARKIN, JEFFREY S

ART UNIT	PAPER NUMBER
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1648

DATE MAILED: 06/12/2002

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/555,640

Applicant(s)

Nguyen, Q. T., et al.

Examiner

Jeffrey S. Parkin, Ph.D.

Art Unit

1648



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 01 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10 Aug 2000.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-14, 16-21, and 24-37 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claims 1-14, 16-21, and 24-37 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

Unity of Invention

35 U.S.C. § 371

1. This application was filed under 35 U.S.C. § 371 and is subject to unity of invention practice pursuant to 35 U.S.C. § 121 and 372. This application contains the following inventions or groups of inventions which are not so linked as to form a single inventive concept under PCT Rule 13.1. In accordance with 37 C.F.R. § 1.499, applicants are required, in response to this action, to elect a single invention to which the claims must be restricted.

a. Group I, claims 1-6 and 10, drawn to **nucleic acids, fragments thereof, and primer pairs.**

b. Group II, claims 7-9, drawn to a **variant erythrovirus** or plasmids encoding said variant.

c. Group III, claims 11-14, 16, and 24-27 drawn to **diagnostic methods** employing various **nucleotide sequences.**

d. Group IV, claims 17-20, 28, 29, drawn to **proteins or polypeptide fragments** thereof and immunogenic compositions containing said proteins or fragments.

e. Group V, claims 21, 30, 31, drawn to an **antibody** directed against an erythrovirus variant protein or polypeptide fragment thereof.

f. Group VI, claims 32 and 33, drawn to **in vitro screening methodologies** employing erythroviral **peptides.**

g. Group VII, claims 34 and 35, drawn to **in vitro screening methodologies** employing erythroviral-specific **antibodies.**

h. Group VIII, claims 36 and 37, drawn to a **diagnostic kit** comprising various reagents.

2. The inventions listed as Groups I-VIII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for

the following reasons: each of the identified groups is directed toward a structurally and functionally different product (e.g., nucleic acids, proteins, antibodies, diagnostic kits) or methodology (e.g., nucleic acid-based, peptide-based, or antibody-based detection assays) which employs structurally and functionally unrelated products and assay steps. Accordingly, the identified groups all lack a special technical feature. Moreover, the claimed invention also fails to make a contribution over the prior art (i.e., see the ISA Chapter I search report). Thus, a special technical feature is not present.

3. Applicants are also advised that multiple inventions lacking a special technical feature exist within each of the identified groups. For instance, the nucleotide sequences set forth in Group I are all structurally and functionally different. SEQ ID NO.: 1 is directed toward a full-length genomic clone of the erythrovirus V9. Other sequence identifiers are directed toward various V9 antigens (e.g., NS1, 7.5 kDa protein, VP1, VP1u, X protein, VP2, 11 kDa protein). Additional nucleotide sequences are directed toward fragments of these sequences, sequences capable of hybridizing to said sequences, and primer pairs capable of amplifying said sequences. Since each of the identified nucleotide sequences have different structures, separate searches will be required for each sequence. The same reasoning extends to the various proteins and antibodies identified in Groups IV and V. Each peptide and antibody set forth within these groups have different structures and functions. Independent searches will be required for each product. Due to the large number of groups identified, each of these are not set forth individually. **Applicants will be required to elect a single product (e.g., a nucleotide sequence comprising SEQ ID NO.: 1, a peptide encoded by SEQ ID NO.: 81, an antibody that binds specifically to the NS1 antigen) for examination on the**

merits. For instance, if Group I is elected, applicants will be required to elect a single nucleotide sequence (e.g., SEQ ID NO.: 1, SEQ ID NO.: 81, a sequence complementary to SEQ ID NO.: 81, a specific PCR primer pair, or a fragment bearing a specific SEQ ID NO.:) for examination. If Group IV is elected, a single peptide (e.g., a peptide encoded by SEQ ID NO.: 81) must also be identified. If Group V is elected, a single antibody (e.g., an antibody that binds specifically to NS1) must be identified. If Group VIII is elected, a specific reagent must also be identified. This is **not** a species election requirement.

4. Applicants are advised that pursuant to 37 C.F.R. § 1.475, if a product is elected, the Examiner would also consider claims directed toward a single method of making said product and a single method of using said product. **If applicants decide to elect a particular methodology, the precise product employed in said methodology must also be identified as set forth supra.** For instance, if Group III is elected, a specific probe or primer pair must also be elected. **Applicants are reminded that the claims should be amended appropriately to reflect the election.** If applicants have any questions concerning this restriction requirement they are invited to contact the Examiner as set forth below.

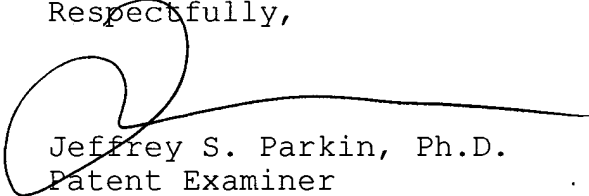
5. Applicants are advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 C.F.R. § 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by

a diligently-filed petition under 37 C.F.R. § 1.48(b) and by the fee required under 37 C.F.R. § 1.17(h).

Correspondence

- 5 6. The Art Unit location of your application in the Patent and Trademark Office has changed. To facilitate the correlation of related papers and documents for this application, all future correspondence should be directed to **art unit 1648**.
- 10 7. Correspondence related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Official communications should be directed toward one of the following Group 1600 fax numbers: (703) 308-4242 or (703) 305-3014. Informal communications may be
- 15 submitted directly to the Examiner through the following fax number: (703) 308-4426. Applicants are encouraged to notify the Examiner prior to the submission of such documents to facilitate their expeditious processing and entry.
- 20 8. Any inquiry concerning this communication should be directed to Jeffrey S. Parkin, Ph.D., whose telephone number is (703) 308-2227. The examiner can normally be reached Monday through Thursday from 8:30 AM to 6:00 PM. A message may be left on the examiner's
- 25 voice mail service. If attempts to reach the examiner are unsuccessful, the examiner's supervisors, James Housel or Laurie Scheiner, can be reached at (703) 308-4027 or (703) 308-1122, respectively. Any inquiry of a general nature or relating to the status of this application should be directed to the Group 1600
- 30 receptionist whose telephone number is (703) 308-0196.

Respectfully,



Jeffrey S. Parkin, Ph.D.
Patent Examiner
Art Unit 1648

10 June, 2002